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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,630	01/28/2002	Michael L. Camilleri	07039-355001	3436

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EXAMINER	
HASHEMI, SHAR S	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 08/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 10/058,630	Applicant(s) CAMILLERI ET AL.	
	Examiner Shar Hashemi	Art Unit 1637	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

P riod f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The sequences lack SEQ. ID. NO identifiers. For example, the two primer sequences disclosed on page 13, lines 10-11, must have SEQ. ID. NO. identifiers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) The abbreviation "5-HTTP" in claims 1, 5, 12, & 14 renders claims 1-14 indefinite. It is unclear as to whether the abbreviation "5-HTTP" refers to the serotonin transporter gene or serotonin transporter linked polymorphic region gene.

B) The term "effective" in claim 12 is relative term which renders the claims indefinite. The term "effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of these claims cannot be established because several parameters determine

"effective" and because no single set of conditions is recognized by the art as being "effective" to the exclusion of all other conditions, the claims are indefinite.

C) The term "sample's 5-HTTP gene" is confusing in claim 12. It is unclear as to whether the term "sample's 5-HTTP gene" refers to a sample obtained from the patient or another source.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-14 are rejected under 35 U.S.C. 102(a) as being anticipated by Kong et al (WO 01/61039 A2 August 23, 2001).

Kong et al in WO 01/61039 A2 teach a method for predicting patient responsiveness to a 5-HT_3 receptor antagonist comprise determining the genotype of the promoter region of the patient's 5-HTTP gene and correlating the genotype with the patient's responsiveness (page 3, lines 15-35; page 4, lines 1-31, page 22, see example 3). They also teach alosetron is the 5-HT_3 receptor antagonist used in the treatment for diarrhea-predominant irritable bowel syndrome (page 4, lines 26-31; page 21, see example 2). In the genotyping step, they teach amplifying a nucleic acid comprising the promoter region of the patient's 5-HTTP gene in order to obtain an amplified product and determining the size of the amplified product to identify a long variant/long variant genotype with patient responsiveness (page 22, see example 3). They teach the long

variant/long variant genotype is related to a greater patient responsiveness than the short variant/long variant genotype (page 19, see example 1). They teach the patient responsiveness is determined by measuring a patient parameter (page 1, lines 19-30; page 2, lines 1-13). They further teach that patient responsiveness is determined by comparing a measured net negative change in the geometric center of colonic transit of at least 1.14 colonic regions after treatment with the 5-HT_3 receptor antagonist (page 2, lines 1-24).

Second, they teach a method for treating a patient with diarrhea-predominant irritable bowel syndrome comprise obtaining a biological sample form the patient, genotyping the promoter region of the patient's 5-HTTP gene and administering a 5-HT_3 receptor antagonist to patient's having a long variant/long variant genotype in the promoter region of the 5-HTTP gene (page 28, see claims 33 & 36). They teach that the biological sample is blood (page 27, line 15).

Third, they teach a method for identifying a patient population for inclusion in a 5-HT_3 receptor antagonist clinical trial comprise obtaining a biological sample form a potential participant in the clinical trial, genotyping the promoter region of the 5-HTTP gene contained within the biological sample, and identifying the potential participant as suitable for inclusion in the patient population based on having a long variant/long variant genotype in the promoter region of the potential participant's 5-HTTP gene (page 21, see example 2).

SUMMARY

4. No claims allowed.

CONCLUSION

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shar Hashemi whose telephone number is (703) 305-4840 and whose e-mail address is shar.hashemi@uspto.gov. However, the Office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can be best reached on weekdays from 7:00 a.m. to 3:30 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Sharon Thornton for Art Unit 1637 whose telephone number is (703)-305-3001.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-1235 and Before Final FAX (703) 872-9306 or After Final FAX (703) 308-9307.

August 25, 2002

Shar Hashemi

Jeffrey Siew
JEFFREY SIEW
PRIMARY EXAMINER
8/26/02